

CLAIMS

1. Use of calcium stearate to inhibit or reduce chemical interaction between an active ingredient substance and a carrier in a solid pharmaceutical formulation, wherein said active ingredient substance is susceptible to chemical interaction with said carrier.
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2. Use of calcium stearate to inhibit or reduce chemical degradation of an active ingredient substance in a solid pharmaceutical formulation comprising the active ingredient substance and a carrier, wherein said active ingredient substance is susceptible to chemical interaction
10 with said carrier.
3. Use as claimed in claim 1 or claim 2 wherein the carrier is a reducing sugar.
4. Use as claimed in claim 3 wherein the carrier is lactose.
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5. Use as claimed in any one of claims 1 to 4 wherein the calcium stearate is present in an amount of from 0.1 to 20% w/w based on the total weight of the composition.
6. Use as claimed in any one of claims 1 to 5 wherein the active ingredient substance is present in an amount of from 0.01% to 50% w/w based on the total weight of the composition.
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7. Use as claimed in any one of claims 1 to 6 wherein the drug substance is one which includes the group Ar-CH(OH)-CH₂-NH-R.
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8. Use according to claim 7 wherein said drug substance is selected from:

3-(4-{{(2R)-2-hydroxy-2-[4-hydroxy-3-(hydroxymethyl)phenyl]ethyl}amino}hexyl)oxy]butyl)
benzenesulfonamide;
30 3-(3-{{[7-((2R)-2-hydroxy-2-[4-hydroxy-3-hydroxymethyl)phenyl]ethyl}-
amino)heptyl}oxy}propyl)benzenesulfonamide;
4-{{(1R)-2-[(6-{2-[(2,6-dichlorobenzyl)oxy]ethoxy}hexyl)amino]-1-hydroxyethyl}-2-
(hydroxymethyl)phenol and
4-{{(1R)-2-[(6-{4-[3-(cyclopentylsulfonyl)phenyl]butoxy}hexyl)amino]-1-hydroxyethyl}-2-
35 (hydroxymethyl)phenol,

or a salt, solvate or physiologically acceptable derivative thereof.

9. Use as claimed in any one of claims 1 to 8 wherein the solid pharmaceutical formulation is for administration by inhalation.

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10. Use as claimed in any one of claims 1 to 9 wherein the solid pharmaceutical formulation comprises two or more active drug substances.

11. An inhalable solid pharmaceutical formulation comprising (a) an active ingredient substance susceptible to chemical interaction with a carrier, (b) a carrier and (c) calcium stearate.

12. An inhalable solid pharmaceutical formulation as claimed in claim 11 further comprising one or more of the features described in any one or more of claims 3 to 10.

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13. An inhalable solid pharmaceutical formulation as claimed in claim 11 or claim 12 wherein the active ingredient substance is 3-(4-{[6-((2R)-2-hydroxy-2-[4-hydroxy-3-(hydroxymethyl)phenyl]ethyl]amino)hexyl] oxy}butyl) benzenesulfonamide; or a salt, solvate or physiologically acceptable derivative thereof, and the carrier is lactose.

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14. A method of reducing or inhibiting chemical interaction between an active ingredient substance and a carrier susceptible to chemical interaction, which comprises mixing calcium stearate with said active ingredient substance and said carrier.

25 15. A method of inhibiting chemical degradation of an active ingredient substance in a formulation comprising a carrier and an active ingredient substance, which method comprises mixing calcium stearate with said active ingredient substance and said carrier.

30 16. A method as claimed in claim 14 or 15 further comprising one or more of the features described in any one or more of claims 3 to 10.

35 17. Use of an inhalable solid pharmaceutical formulation as claimed in any of claims 11 to 13 for the manufacture of a medicament for the treatment of asthma, chronic obstructive pulmonary disease (COPD), chronic or wheezy bronchitis, emphysema, respiratory tract infection, upper respiratory tract disease or rhinitis, including seasonal and allergic rhinitis.

18. A method for treating asthma, chronic obstructive pulmonary disease (COPD), chronic or wheezy bronchitis, emphysema, respiratory tract infection, upper respiratory tract disease, or rhinitis, comprising administering to a patient in need thereof an inhalable solid
5 pharmaceutical formulation as claimed in any of claims 11 to 13.

19. A method of preparing a solid pharmaceutical preparation comprising combining in one or more steps: (a) an active ingredient substance susceptible to interaction with a carrier, (b) a carrier and (c) calcium stearate.